

ART 34 AMDT**CLAIMS:**

1. An oral appliance for placing in a mouth of a user, the appliance including:
 - 5 a base member having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member having inner and outer flanges interconnected by a web which define at least one of upper and lower channels within which the corresponding rows of teeth of a user are received; and
 - 10 a continuous layer of thermoplastic material that encompasses the base member thereby to firmly and securely mount the layer of thermoplastic material on the base member, the layer of thermoplastic material forming teeth engaging elements which can be conformed or moulded to suit the individual teeth of a user by heating to a temperature at which the layer is plastic and formable.
- 20 2. An oral appliance according to claim 1, wherein the base member defines an upper channel within which the upper row of teeth of a user is received.
- 25 3. An oral appliance according to claim 1, wherein the base member defines both upper and lower channels within which respectively the upper and lower rows of teeth of a user are received.
4. An oral appliance according to any one of claims 1 to 3, wherein the layer of thermoplastic material is EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C and the base is made out of a reasonably rigid plastics material.
- 30 5. An oral appliance according to any one of claims 1 to 4, wherein the layer of thermoplastic material forming the teeth engaging elements has a thickness of 1mm – 3mm.

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6. An oral appliance according to any one of claims 1 to 5, wherein said continuous layer of thermoplastics material substantially covers the full surface area of the base member.

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7. An oral appliance according to any one of claims 1 to 6, wherein a tongue tag is formed on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use.

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8. An oral appliance according to any one of claims 1 to 7, wherein the base member has breathing apertures defined therein for facilitating breathing by a user when wearing the appliance.

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9. An oral appliance according to any one of claims 1 to 8, wherein the base member is made of a non-thermoplastics material.

10. An oral appliance according to claim 9, wherein the base member is made from polyurethane, polypropylene, or santoprime.

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11. A method of manufacturing an oral appliance for placing in the mouth of a user, the method including the steps of:

moulding a base member from plastic material in a first moulding step in a first mould, the member having a generally U-shaped form corresponding to the outline of the jaw of a user and inner and outer flanges interconnected by a web which define at least one of upper and lower channels within which the corresponding rows of teeth of a user are received;

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removing the base member from the first mould and placing it in a second mould having a larger mould cavity and moulding a continuous layer of thermoplastic material onto the base member to form upper and lower teeth engaging elements capable of being

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customised to suit the mouth of a user , the layer encasing the member to thereby firmly and securely mount the layer of thermoplastic material on the base member.

- 5 12. A method according to claim 11, wherein the base member defines an upper channel within which the upper row of teeth of a user is received.
13. A method according to claim 11, wherein the base member defines both upper and lower channels within which respectively the upper and lower
- 10 rows of the teeth of a user are received.
14. A method according to any one of claims 11 to 13, wherein the continuous layer of thermoplastic material is moulded substantially fully across the surface area of the base member in said second moulding step.
- 15 15. A method according to any one of claims 11 to 14, wherein the base member is injection moulded from polyurethane, polyethylene, polypropylene or santoprime.
- 20 16. A method according to any one of claims 11 to 15, wherein the layer of thermoplastic material is injection moulded from EVA while it is locked in position in the second mould.

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